Defending Against the Next Wave of Biosimilars

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The first wave of biosimilars (filgrastim) launched with much fanfare but little impact on total drug spend. The second wave is now bringing biosimilars of major blockbusters in oncology (Rituxan, Herceptin, Avastin) and autoimmune diseases (Remicade, Humira, Enbrel) to markets worldwide. While uptake has varied across molecules and geographies, the U.S. remains particularly undeveloped. With the third biosimilar wave beginning in 2020, how can originators prepare to face the competition?

Strategically, we see three reference product manufacturer archetypes emerging:

**Market Terraformers**
Those committed to meaningfully shaping the biosimilar landscape and fervently defending against erosion, sometimes by launching their own biosimilars. Alternatively, some may seek to discourage biosimilar entrants entirely.

**Diligent Defenders**
Those compellingly defending against biosimilar erosion for their vulnerable assets yet unwilling to make investments on a grand scale to shape the biosimilar category.

**Laissez-Faire Expeditioners**
Those not meaningfully defending their impacted assets, likely due to acquiescence that loss of exclusivity (LOE) means deep erosion and prioritization of newer molecules as they explore new areas.

The appropriate strategic choice for a manufacturer depends on many factors, including appetite for risk, portfolio composition and relationships with critical market shapers. There is no one-size-fits-all approach for biosimilar defense.

To that end, if your organization is likely a market terraformer or diligent defender, or a laissez-faire expeditioner with some level of consideration for the risk of your next-generation strategy succeeding, what should defense look like?
Planning a Defense Against Biosimilar Entry

The minimum time frame to prepare as a defender is 24 months prior to the earliest possible biosimilar launch. A more robust window is closer to five years. The necessary lead time for planning a defense strategy depends on the role that the company wants to play in shaping the market and defending sales.

If the company is nimble, prepared to make rapid decisions and accustomed to aggressive competition, and if the product doesn’t represent a large portion of the portfolio, then two years may be enough. If the opposite is true for each of those factors, companies should aim to add at least one year to their preparation runway. Of course, if the primary defense strategy is life cycle management planning (for example, a next-generation asset launching to replace the defending asset), that strategy requires at least 10 years in advance of biosimilar entry. However, it’s risky to rely on a next-generation asset as the only defense strategy given the inherent uncertainty in clinical development. Even if the next-generation product launches on time, their manufacturers should not underestimate the challenge of converting prescribers to the new product, particularly if the existing product deeply penetrates a therapy area.

In most cases, the initial planning for biosimilar defense should begin at least three years before the earliest potential biosimilar approval. We recommend anchoring to the approval date rather than the launch date because biosimilars may receive FDA approval before the reference product’s LOE. In this case, biosimilar manufacturers could begin market preparation and promotional activities after approval but before launch, so long as they don’t ship any product. The reference product manufacturer will want to be ready with defense tactics and counter messages—at an absolute minimum—at the time of the first biosimilar approval.

Some reference products have considered product formulation changes as a key biosimilar defense strategy. Any manufacturer considering a change in formulation (such as changing from an infusion to an injection, like Rituxan) should start that evaluation at least five years ahead of LOE given the required time for clinical trials, regulatory filing, manufacturing capacity development and customer conversion.
Biosimilar competition is disruptive and unpredictable: Not quite a true brand or a generic, it’s tough to predict what a biosimilar launch situation or go-to-market strategy will look like. We have examples to draw upon but no perfect analogues for each upcoming situation. It’s imperative to gather more customized insights related to a specific situation early to plan for varying biosimilar scenarios.

Often, it’s challenging to predict specific biosimilar launch timing due to patent law interpretation/clinical trial and regulatory uncertainty. For true competitive readiness, reference product manufacturers must prepare for multiple biosimilar launch scenarios. Beyond launch timing, manufacturers should consider variable labelling scenarios (“carve out” or “skinny label”) or extrapolation status and competitor strategies in their scenario planning efforts.

Still unconvinced that defense planning years in advance of biosimilar approval is necessary? We see four primary risks to planning too late:

1. **Organizational inertia**: Especially for large organizations competing with nimbler organizations, failing to plan in advance could limit tactical options. Designing and implementing a new program requires cross-functional input, and organizations often underestimate the time required to gain alignment and execute their ideas.

2. **Ceding the first-mover advantage to the biosimilar manufacturer**: Reference product manufacturers will typically want to delay offering discounts or rebates to payers for as long as possible to protect their current revenue stream. However, biosimilar manufacturers might negotiate pricing or innovative contracting arrangements with payers to support product uptake even before they’ve formally launched. In this case, by delaying the start of negotiations with payers, reference products could unnecessarily cede the first-mover advantage to the biosimilar manufacturer.

3. **Communication to prescribers**: Even once a reference manufacturer has finalized a contract, the manufacturer will need to communicate the formulary status to prescribers. Many prescribers assume that payers will prefer the biosimilar over the reference product because of an assumed lower price, so it’s incumbent on reference manufacturers to assure physicians of continued access to their products even after the biosimilars launch.
Developing a Biosimilar Defense Program

The relevant workstreams will vary significantly from market to market as a function of the competitive landscape and a manufacturer’s existing strategic planning processes. Companies with strong life cycle planning and global engagement will start this work well in advance of the timeline mentioned above, making the largest change transferring the work from the life cycle team to the country leads. With that in mind, key focus areas include:

+ Biosimilar adoption insight gathering (What has the landscape looked like so far?)
+ Scenario identification and prioritization
+ Long- and short-term forecasting (consider a “bottoms up” forecast in addition to more traditional top-down forecasting)
+ Portfolio planning and individual brand positioning
+ Customer segmentation (HCP and account/site of care)
+ Competitive “war gaming”
+ Contracting and pricing strategy
+ Organization design, including field and headquarters
+ Readiness reviews and tactical planning
+ Executional excellence (agile operations and analytics to track market evolution and pivot as needed)

The approval of a biosimilar for any product has the potential to shape the market significantly. Without careful strategic planning, it’s possible for reference product manufacturers to put hundreds of millions of dollars at risk. When a major market category is as uncertain as the biosimilar market is today, advance strategic planning is a necessity, not just a “nice to have.” If your product might face biosimilar competition in the third wave (2020 to 2030), what can you do today to get ready?
About the Authors

Christina Corridon is an associate principal in ZS’s Boston office and is the leader of the biosimilars vertical at ZS. She has more than a decade of experience working in the pharmaceutical and biotech industries, with specific expertise in oncology and biosimilars. During her consulting career, she has worked on U.S. and global projects spanning many facets of commercialization strategy, including launch strategy and planning, go-to-market strategy, commercial models, marketing strategy and brand planning.

David Weil is an associate principal in ZS’s San Francisco office. He has more than 14 years of experience advising clients in the pharmaceutical and biotechnology industries on a range of sales and marketing issues. With a focus on oncology and biotech clients, David specializes in competitive strategy, product life cycle planning, biosimilars strategy, and maximizing value on the people side of our clients’ business.

Gustavo Poblete is an associate principal in ZS’s San Francisco office. He focuses exclusively on issues related to market access, pricing, and contracting strategy and analytics. Gustavo has 10 years of experience in the pharmaceutical/biotech space in the U.S. and Latin America, and he has worked with more than 15 pharmaceutical firms (eight of the top 10). The first half of his career was dedicated primarily to sales force sizing and structuring, resource allocation, customer segmentation and valuation, targeting and call planning. Now, his particular focus is on medical benefit specialty drugs.

Tucker Herbert is a manager in ZS’s Los Angeles office. He has advised major biotechnology firms on a broad range of sales and marketing strategy issues, with an emphasis on oncology and biosimilars. His experience has focused on global quantitative and qualitative primary market research and secondary data analytics. In addition, Tucker was one of the founding members of ZS’s biosimilars vertical, and has led more than 30 training sessions across North America and Asia on the topic.
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